K093375

EXHIBIT #1

510(k) Summary

DEC - 2 2009

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

1. **Applicant:**
   Koon Seng Sdn. Bhd.
   Ptd 16058, Kawasan Perindustrian Tangkak,
   Jalan Muar, 84900 Tangkak, Johor,
   Malaysia

2. **Manufacturer:**
   Koon Seng Sdn. Bhd.
   Ptd 16058, Kawasan Perindustrian Tangkak,
   Jalan Muar, 84900 Tangkak, Johor,
   Malaysia

3. **Submitter:**
   Mr. Jigar Shah
   Official Correspondent for
   Koon Seng Sdn. Bhd.
   Summary Prepared on: April 7, 2009

4. **Address:**
   mdi Consultants, Inc.
   55 Northern Blvd., Suite 200
   Great Neck, New York 11021
   Tel: 516-482-9001
   Fax: 516-482-0186
   jigar@mdiconsultants.com

5. **Trade/proprietary Name:**
   'KS-CARE' Powder Free Polymer Coated Latex Examination Glove with Protein Content labeling Claim (50 Micrograms or Less).

6. **Common Names:**
   POWDER-FREE Patient Examination Glove

7. **Classification name:**
   Patient Examination Glove

8. **Classification number:**
   21 CFR 880.6250

9. **Device Description:**
Powder free Latex Examination Glove is a class I device having product code LYY. It is a disposable device that meets all requirements of ASTM D3578-05.

10. **Intended Use:**
A powder free patient examination glove is a disposable device intended for medical purposes that is worn on the examiners hand or finger to prevent contamination between patient and examiner. These gloves are not intended to be used as a chemical barrier.

11. **Substantial Equivalence Discussion:**

A powder free patient examination glove is substantially equivalent to the predicate devices.

Characteristic and parameters	**'KS-CARE' Powder Free Polymer Coated Latex Examination Glove with Protein Content labeling Claim (50 Micrograms or Less)**	**SGMP Company Ltd. Powder-free Latex Examination Gloves 510K # K071060**	**Pt. Maja Agung Latexindo Powder-free Latex Examination Gloves 510K # K081488**	**Substantial Equivalence (SE)**
Product Code	LYY	LYY	LYY	
Intended Use	A powder free patient examination glove is a disposable device intended for medical purposes that is worn on the examiners hand or finger to prevent contamination between patient and examiner.	A powder free patient examination glove is a disposable device intended for medical purposes that is worn on the examiners hand or finger to prevent contamination between patient and examiner.	A powder free patient examination glove is a disposable device intended for medical purposes that is worn on the examiners hand or finger to prevent contamination between patient and examiner.	SE
Width (size medium)	95 +/- 5 mm	90-97mm	95 +/- 5 mm	SE
Overall length	Min 240 mm	241 mm	240 mm	SE
Palm thickness	Min 0.08 mm	0.10 mm	0.10 mm	

Finger thickness	Min 0.08 mm	0.13 mm	0.10 mm	Minor difference
Tensile strength pre aging min	Min 18 Mpa	27 mpa	18 mpa	
Tensile strength after aging min	Min 14 Mpa	25.8	14 mpa	
Ultimate elongation pre aging min	Min 650%	830%	650%	
Ultimate elongation after aging min	Min 500%	730%	500%	
Meets Biocompatibility	YES	Yes	Yes	SE
Duration of bio-compatibility	Except product change			
Skin irritation test	Pass	Pass	Pass	SE
Dermal sensitization	Pass	Pass	Pass	
AQL	1.5%	2.5%	NA	SE
Residual Powder Content	Max 2.0mg/glove	1.1 mg /glove	NA	SE
Residual Protein Level	< 50 µg/g	‹ 50 µg/ dm^2	NA	SE

12. Summary of Testing:

Test	Results
a. Dermal Sensitization Test	Passes
b. Primary Skin irritation	Passes
c. Iodine Test	Passes
d. Tensile strength	Gloves meets the requirements of ASTM D3578-05.

The standards used by Koon Seng Sdn. Bhd. to determine substantial equivalence is based on ASTM D3578-05a. All testing meets requirements for physical specifications and dimensions conducted on gloves, Inspection level S-2, AQL 4.0, pinholes at AQL 2.5

We do not claim our gloves to be hypoallergenic.

13. Conclusion:

'KS-CARE' Powder Free Polymer Coated Latex Examination Glove (with Protein Content labeling) performance was equivalent to any other conventional method evaluated. Our evaluation concluded that our device raises no new issues of Safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

DEC - 2 2009

Koon Seng Sdn. Bhd.
C/O Mr. Jay Y. Kogoma
Responsible Third Party Official
Intertek Testing Services NA, Incorporated
2307 East Aurora Road, Unit B7
Twinsburg, Ohio 44087

Re: K093375
Trade/Device Name: Powder Free Polymer Coated Latex Examination Glove with Protein Content Labeling Claim (50 Micrograms or Less)
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LYY
Dated: November 17, 2009
Received: November 18, 2009

Dear Mr. Kogoma:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Anthony D. Watson for

Susan Runner, D.D.S., M.A.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

EXHIBIT #3

Indications for Use

510(k) Number (if known): K 09 3375

Applicant: Koon Seng Sdn. Bhd.

Device Name: Powder Free Polymer Coated Latex Examination Glove with Protein Content Labeling Claim (50 Micrograms or Less)

Indications for Use:
A powder free patient examination glove is a disposable device intended for medical purposes that is worn on the examiners hand or finger to prevent contamination between patient and examiner.

Prescription Use_____ **AND/OR** **Over-The-Counter Use** X
(Part 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth F. Claverie - Wilson

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K 093375